AUG 2 5 2000

K002200

510(k) Summary
Summary of Safety and Effectiveness

Submitter

Name and address: Madsen Electronics
5600 Rowland Road
Minnetonka, MN 55343
Phone: 612-930-0416
Fax: 612-930-0516
Contact person: Jim Bergerson

Summary prepared: June 23, 2000

Device name

Common/Usual name:	AudioDiagnostic Testing System
Trade/Proprietary name:	Capella
Classification name:	Audiometer

Predicate devices

Capella is identical to the product Capella Cochlear Emissions Analyzer (#K983851) except that two additional tests are available: Otoacoustic emissions screening and Tympanometry.

Otoacoustic emissions screening is performed by Echo-Screen (#K982642) and tympanometry is a part of immitance test which is performed by Zodiac 901 Middle-Ear Analyzer (#K910247).

Description

Capella is a PC-based system, which consist of software modules for installation on an IBM or compatible PC, a hardware platform, a probe assembly and a probe attached to the probe assembly. The probe assembly is connected to the hardware platform, which is connected to the PC via a serial COM port.

Capella is operated from the PC software modules that control measurements performed by the hardware platform and display test results for analysis by the operator.

The hardware platform is available in two power source variants (mains and battery version) and two probes are available: one for otoacoustic emissions and tympanometry and one for Echo-Screen mode.

Design characteristics:
Hardware platform (mains and battery version):
Size 305x284x59 mm (WxDxH), weight 1.8 kg
Power supply: AC 50/60 Hz, 100-240 V
Battery: 7.2 V/3800 mAh, rechargeable (only battery version)
Probe assembly: Weight 73 g
Standard probe: Weight 14 g
Echo-Screen probe: Weight 4 g

Intended Use
The purpose of Capella is to test the cochlear function of infants, children and adults. The presence of otoacoustic emissions indicates cochlear function.

Capella is intended for measurement of otoacoustic emissions (Distortion Product otoacoustic emissions DPOAE, Transient Evoked otoacoustic emissions TEOAE and Spontaneous otoacoustic emissions SOAE), otoacoustic emissions screening based on TEOAE, and tympanometry.

Capella's tympanometry performs a check of the middle-ear function to eliminate middle-ear problems from OAE diagnostics.

Capella is intended to be used by trained personnel in a hospital, nursery, ENT clinic or audiology office.

Technological Characteristics

Device Specifications	**Capella**	**Capella (K983851)**
Safety compliance	EN 60601-1	EN 60601-1
Construction type	PC-based system	PC-based system
Power source	Mains and battery Rechargeable battery	Mains and battery Rechargeable battery
Battery low indication	Message on display	Message on display
Computer interface	RS232 communication	RS232 communication

OAE	Tones/clicks are presented to the ear via the probe. The response from the cochlea of ear is received and registrated. Tone/click is controlled via SW and HW and is limited to max. output level 90 dB SPL.	Tones/clicks are presented to the ear via the probe. The response from the cochlea of ear is received and registrated. Tone/click is controlled via SW and HW and is limited to max. output level 90 dB SPL.
Tympanometry	Probe tone is presented to the ear via the probe. The response reflects the acoustic immitance. Change of the acoustic immitance is registrated as a function of air pressure in the external ear canal. Probe tone is controlled via SW and HW and is limited to max. output level 90 dB SPL. Air pressure is controlled via SW and HW and is limited to the range: +200 to –400 daPa.	
Standard probe	OAE: Two speakers present stimulus and a microphone record the response. Tympanometry: Pipe for air pressure. One speaker and microphone present and control probe tone level.	OAE: Two speakers present stimulus and a microphone record the response.
Echo-Screen probe	One speaker present stimulus and a microphone record the response.	
Probe assembly	OAE: Preamplifier for probe microphone. Tympanometry: Pressure transducer for control of air pressure generated in hardware.	OAE: Preamplifier for probe microphone

Software	C-based SW controls HW and display test results	C-based SW controls HW and display test results
Supporting software	NOAH and PAX database SW	NOAH and PAX database SW

Tympanometry in Capella and Zodiac 901 is identical except that air pressure range is reduced from [+400 to –600 daPa] to [+200 to –400 daPa].

Standard probe and probe assembly for tympanometry in Capella and Zodiac 901 is identical except that speaker and microphone is build into the Capella probe.

Echo-Screen probe for otoacoustic emissions screening in Capella and Echo-Screen is identical.

Safety

Capella is designed to provide safety to the patient as well as the user and complies with EN 60601-1 (General safety), EN 60601-1-2 (EMC), EN 60601-1-4 (Programmable systems) and Medical Devices Directive 93/42/EEC. Capella is build to conform with UL 2601-1 and UL listing is pending.

Capella complies with product standard EN 61027 and ANSI S3.39 for the tympanometry portion design and calibration procedures.

Capella is designed, developed and manufactured according to EN ISO 9001 (Quality Systems) and EN 46001 (Quality Systems - Medical devices).

To prevent excessive sound level and air pressure within the ear, the software and hardware controls the maximum output sound level to 90 dB SPL and the maximum air pressure to +200 and –400 daPa. The hardware is built in such a way that the system is incapable of producing enough sound level and air pressure to permanently damage the ear.

Effectiveness

Capella is a PC-based OAE system for testing the cochlear function which also provides a check of the middle-ear function to eliminate middle-ear problems from OAE diagnostics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2000

Mr. Jim Bergerson
Service and Technology Manager
Madsen Electronics, Inc.
5600 Rowland Road
Minnetonka, MN 55343

Re: K002200
Trade Name: Capella
Regulatory Class: II
Product Code: 77-EWO
Dated: June 29, 2000
Received: July 20, 2000

Dear Mr. Bergerson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications for Use

Capella is indicated for use in testing the cochlear function of infants, children and adults in a hospital, nursery, ENT clinic or audiology office. It measures otoacoustic emissions (OAE's) which allows the operator to get information about hearing sensitivity without a subjective response from the individual being tested. The presence of otoacoustic emissions indicates cochlear function.

Capella's tympanometry performs a check of the middle-ear function prior to performing OAE measurements.

James K Kane

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002200